

REMARKS

Reconsideration and continuing examination of the above-identified application is respectfully requested in view of the amendments above and the discussion that follows.

Claims 1, 9, 14, 16, 23, 25, 27, 34, 35, 36, 42, 53, 56, 57, 58, 60, 61, 63, 64 and 65 have been amended. Claims 47 and 66 were cancelled previously. Claims 3, 4, 5, 12, 13, 18, 21, 29, 30, 31, 38, 39, 50, 52, 55, 59, and 68-75 are cancelled herein to speed prosecution. Claims 1-2, 6-11, 14-17, 19, 20, 22-28, 32-37, 40-46, 48-49, 51, 53, 54, 56-58, 60-65 and 67 are in the case and are before the Examiner.

A. The Amendments

The present Reply and Amendment maintains the amendments made in the paper filed on December 18, 2003, and clarifies that the indented B cell epitope is a repeated *P. falciparum* peptide sequence pursuant to the Examiner's helpful comments in the Advisory Action mailed January 28, 2004. In addition, the present amendment corrects some inadvertent errors made in the prior response.

The previous amendment to claim 27 paragraph (d) has been noted to have omitted the underlining of subparagraph (i) to indicate the addition of that phrase and the deletion of the proviso phrase at the end of that paragraph. That paragraph also included to subparagraphs (ii). Each of those inadvertent errors has been corrected herein. Previously amended claim 60 contained similar inadvertent errors in paragraph (d) subparagraph (ii) and the proviso clause and those errors have also been corrected herein.

The claims have been amended to eliminate the recitation of the phrase "consisting essentially of", whose use was objected to in this and the previous Action. That eliminated phrase is replaced by the words "comprising" or "of an" as are recited at least in original claim 1. Claims 1, 9, 27, 35, 56, 60, 61 and 64 have also been amended to recite that "no more than 10 percent [or 5 percent for claims 61 and 64] of the HBc amino acid residues are substituted as compared to SEQ ID NO:170 from position 1 through 149". These amendments are supported at least by the disclosures at pages 40 through the top of page 42.

Claims 1, 9, 16, 27, 35, 36, 42, 56, 57, 60, 61, 63, and 64 have been amended to speed prosecution so that only sequences of *Plasmodium falciparum* are claimed as is supported through out most of the specification and in at least original claims 30, 49 and 58.

Paragraph (d) of each of claims 9, 35, and 61 has been amended to recite that "one to three cysteine residues" are present in Domain IV as was recited at least in original claims 23 and 53. Claims 23 and 53 have been amended to recite that the one to three cysteines present is "within about 30 residues of the carboxy-terminus of the chimer molecule", as is recited at least in the first full paragraph of page 35.

Each of the independent claims has also been amended to recite that the B cell epitope contains the repeated amino acid residue sequence NANP, using single letter code. This recitation is supported at least by the data I Table 5 of the specification, but also in original claims 3 and 13, that have been cancelled herein.

Claim 25 has been amended to cancel the T cell epitope of *P. vivax* (SEQ ID NO: 25) that was inadvertently left in the claim in the prior reply. That sequence was replaced with a *P. falciparum* T cell epitope sequence of SEQ ID NO: 24 that is shown at least at page 36 in Table B, and in original claims 51 and 58.

The recitation of specific B cell epitopic sequences of claims 56 and 64 have been amended to recite only the *P. falciparum* sequences (SEQ ID Nos:1-14), as the prior Reply overlooked the fact that the previously recited sequences 1-21 inadvertently included some *P. vivax* sequences.

It is thus seen that no new matter has been added.

B. The Action

Each of the bases for rejection or objection will be dealt with in hereinafter in the order of appearance in the Action.

1. Rejection Under 35 U.S.C. §112,

Second Paragraph; "Consists Essentially Of"

Several claims were continued to be rejected as allegedly being indefinite for their use of the phrase "consists essentially of" in regard to an amino acid residue sequence of Domain III. The Action asserted that the language was not clear because the remaining claim language requires that Domain III be bounded on the upstream side by HBC residue 85 and on the downstream side by HBC residue 136, and the "consisting essentially of" phrase implied the "other residues may be inserted at either end of the disclosed range...that would not affect the described peptide." It was thus said to be unclear "what other residues

may be included..." in view of the upstream and down stream boundries. A citation to MPEP § 211.03 was made to support this basis for rejection. Unfortunately, that section does not exist, and it is believed that MPEP § 2111.03 was intended.

Although this basis for rejection cannot be agreed with and the specification at page 39 through the top of page 42 discloses that there can be substitutions and deletions to any given HbC sequence thereby providing the required support for the asserted language, all of the claims that contained the language to which this objection was raised, as well as the use of the phrase for which there was no present objection, have been amended to speed prosecution by removing the allegedly offending language and replacing thast language with other language to which no objection was raised. It is thus believed that the original intent of the language as expressed at pages 39-42 has been maintained while making this rejection is moot.

2. Rejection Under 35 U.S.C. §112,

First Paragraph; Description Requirement

This rejection is similar to that discussed above under the Second Paragraph of Section 112 regarding the use of the phrase "consisting essentially". Again, although the rejection cannot be agreed with, the previously discussed amendments made to speed prosecution are believed to have made the rejection moot.

3. Rejection Under 35 U.S.C. 103

A. First Rejection

The Action rejected all of the claims, except claims 5, 62, and 63, over the combined teachings of Pumpens in view of

Nardin PCT, Nardin, Schödel, Bernardi, Kratz and Metzger in a manner somewhat similar to that of the last Action. The gist of the Action's argument is understood to be the unexpected results documented in the specification and noted in the prior Reply did not necessarily extend to all constructs containing Plasmodium CS protein sequences, including the *P. berghei* sequence that Pumpens teaches in Table 4 of the relied-on Pumpens et al. paper. Although the rejection cannot be agreed with, it is believed that the present amendments that limit the claimed subject matter to *P. falciparum* repeated sequences to speed prosecution here makes this basis for rejection moot.

B. Second Rejection

The Action rejected the pending claims such as claim 5 that include a *P. vivax* CS protein sequence over the previously noted art further along with the disclosures of Colman et al. (Colman) U.S. Patent No. 5,614,194 that discloses use of a *P. vivax* sequence. Here, it is said to be obvious to use a sequence as disclosed by Colman in a chimeric protein suggested by the other teachings. It is again believed that this rejection is moot in view of the present amendments.

C. Summary


Claims 1, 9, 14, 16, 23, 25, 27, 34, 35, 36, 42, 53, 56, 57, 58, 60, 61, 63, 64 and 65 have been amended. Claims 47 and 66 were cancelled previously. Claims 3, 4, 5, 12, 13, 18, 21, 29, 30, 31, 38, 39, 50, 52, 55, 59, and 68-75 are cancelled herein to speed prosecution. Each basis for rejection or objection has been dealt with and overcome or made moot.

It is therefore believed that this application is in condition for an action on the merits and for allowance of all of the claims. An early notice to that effect is earnestly solicited.

A Petition for a One-Month Extension of Time and a Notice of Appeal and their respective fees are enclosed so that the Examiner will have sufficient time to consider the application. No further fee or petition is believed to be necessary. However, should any further fee be needed, please charge our Deposit Account No. 23-0920, and deem this paper to be the required petition.

The Examiner is requested to phone the undersigned should any questions arise that can be dealt with over the phone to expedite this prosecution.

Respectfully submitted,

By 
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CERTIFICATE OF MAILING

I hereby certify that this Second Reply and Amendment After Final, the Petition for a One-Month Extension of Time and its fee, and a Notice of Appeal and its fee are being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, Mail Stop AF, Washington, D.C. 20231 on February 20, 2004.

By 
Edward P. Gamson